

REMARKS

Claims 52-57, 59-63, and 65-69 are pending. No amendments have been made, but a clean set of claims is presented for the convenience of the Examiner.

Request to Withdraw FINALITY

The Applicants respectfully request that the FINALITY of the last Official Action be withdrawn, since new art and rejections were applied and these rejections were not necessitated by amendment. For example, the Office has not explained why the double patenting rejection could not have been lodged on the prior claims.

Rejection—35 U.S.C. §112, second paragraph

Claims 52, 54-57 and 59-53 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. The phrase “nucleotides or base pairs” includes single stranded (“nucleotides”) and double stranded (“base pairs”) polynucleic acids. The term “base pairs” conventionally refers to complementary double-stranded polynucleotides. This interpretation is also clear from the dependent claims which refer to single-stranded (Claim 53) and double-stranded (Claim 67) polynucleotides.

Rejection—35 U.S.C. §102

Claims 52, 53, 56 and 63 were rejected under 35 U.S.C. 102(e) as being anticipated by Clark et al., WashU Zebrafish EST Project (1998). The Applicants traverse this rejection, since the present claims require that the CG nucleotides in the recited sequence not be methylated. Clark et al. is silent with regard to the methylation of these bases. Also, the cDNA sequence of this document is contained within the pT7T3 vector which would increase its length well beyond its disclosed 97 base pairs.

Moreover, the Office has not asserted any factual reason for presuming that the prior art sequence is “inherently immunostimulatory” or that it is present in a composition or in an amount sufficient to exert an antitumor activity.

To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill, Continental Can. Co. USA v. Monsanto Co., 20 USPQ2d 1746, 1749 (Fed. Cir. 1991), see also MPEP 2131.01 (III). In the present rejection, the Office has not established that the missing characteristics (i.e., non-methylation of CG and immunostimulatory activity) are necessarily present in the DNA sequence of Clark. Furthermore, the prior art recognizes that “nonmethylated CG motifs. . .are under-represented in mammalian DNA”, see Kuramoto et al., Jpn. J. Cancer Res. 83:1128 (1992) cited on page 3, lines 8-9 of the specification. Based on this teaching, it is more likely than not that the Clark sequence is methylated and the Office does not have a reasonable basis for asserting that this sequence is not methylated. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of the result or characteristic. In re Rijckaert, 28 USPQ2d 1955 (Fed. Cir. 1993) (M.P.E.P. 2112).

With regard to Claims 53, 66, 68 and 69, the 97 base pair cDNA of Clark is not single-stranded as required by Claim 53, nor is it stabilized as required by Claims 66 and 68. Furthermore, Clark does not disclose a treatment method as required by Claim 69. Under 35 U.S.C. Section 102, every limitation of a claim must identically appear in a single prior art reference for it to anticipate the claim. In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Accordingly, the Applicants respectfully request that the rejection be withdrawn.

Rejection—Double Patenting

Claims 59-62 and 69 were rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 15-19 and 23-26 of U.S. Patent No. 7,108,844. The Applicants respectfully request clarification of the rejection, since this patent only has Claims 1-9. Independent Claim 1 is directed to a method of treating a solid tumor comprising administering a stabilized oligonucleotide having the AACGTTAT motif, where the CG is not methylated. The Applicants respectfully request that this rejection be held in abeyance pending the identification of otherwise allowable subject matter. At that time, if necessary, a terminal disclaimer may be filed.

Allowable Subject Matter

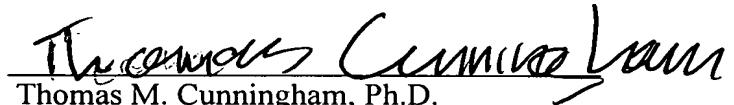
The Applicants thank Examiner Zara for indicating that the subject matter of Claim 65 is otherwise in condition for allowance.

Conclusion

In view of the above remarks, the Applicants respectfully submit that the present application is in condition for allowance. Early notice to this effect is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon

  
Thomas M. Cunningham, Ph.D.  
Registration No. 45,394

Customer Number  
22850

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 06/04)